AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

by,'' or an equivalent term is prominently placed in connection therewith.

(d) *Permittees.* The name and address of the permittee and any statement, design, or device shall not be placed on the labels or containers of a biological product imported for sale and distribution in accordance with §104.5 in a manner which could be false or misleading or which could falsely indicate that the permittee is the manufacturer of such product. The manufacturer shall be identified by name and address with the term ''manufactured by,'' ''produced by,'' or an equivalent term prominently placed in connection therewith. Reference to the permittee shall be made by name, address, and permit number with the term ''imported by,'' ''produced for,'' or an equivalent term prominently placed in connection therewith.

[50 FR 46417, Nov. 8, 1985, as amended at 59 FR 43445, Aug. 24, 1994]

§ 112.5 Review and approval of labeling.

Labels used with biological products prepared at licensed establishments or imported for general distribution and sale must be submitted to the Animal and Plant Health Inspection Service for review for compliance with the regulations and approval in writing prior to use, except as provided in paragraph (c) of this section and under the master label system provided in paragraph (d) of this section.

(a) Transmittal forms, available on the Internet at (*http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml*), shall be used with each submission of sketches (including proofs) and labels. Separate forms shall be used for each biological product but only one copy of the form shall be used for all sketches and labels submitted at the same time for the same biological product.

(b) Sketches may be submitted for comment to Animal and Plant Health Inspection Service by the licensee or permittee before preparing the finished label. Such sketches shall be returned to the licensee or permittee with comments, if any. Failure of the reviewer to take exception to a sketch shall not constitute approval of a finished label subsequently prepared.

(c)(1) Labels must be submitted to the Animal and Plant Health Inspection Service for review and written approval. Only labels which are approved as provided in §112.5(d) may be used. When changes are made in approved labels, the new labels shall be subject to review and approval before use: *Provided,* That certain minor changes may be made in labels for products with approved labels or master labels, and the revised labels may be used prior to review by APHIS, with the provision that a new label or master label bearing these changes is submitted to APHIS for review and written approval within 60 days of label use, and that such minor changes do not render the product mislabeled or the label false and misleading in any particular.

(2) Minor label changes that may be made under the provision for products with approved labels or master labels are:

(i) Changes in the physical dimensions of the label provided that such change does not affect the legibility of the label;

(ii) Change in the color of label print, provided that such change does not affect the legibility of the label;

(iii) The addition or deletion of a Trade Mark (TM) or Registered (R) symbol;

(iv) The correction of typographical errors;

(v) Adding or changing label control numbers of bar codes; and

(vi) Revising or updating logos.

(d) Labels and sketches submitted shall be prepared in the number and manner prescribed in this paragraph.

(1) Copies required:

(i) For label sketches, submit two copies of each sketch of a final container label, carton label, and enclosure. Sketches must be legible, and must include all information specified in §112.2. One copy of each sketch will be returned with applicable comments, and one copy will be held on file by APHIS for no more than one year after processing, until replaced by a finished label: *Provided,* That sketches submitted in support of an application for a license or permit shall be held as long as the application is considered active.

(ii) For master label sketches, submit for each product two copies of each

sketch of an enclosure, label for the smallest size final container, and carton label; *Provided,* That labels for larger size containers and/or cartons that are identical, except for physical dimensions, need not be submitted. One copy of each master label sketch will be returned with applicable comments, and one copy will be held on file by APHIS for one year after processing, until replaced by a finished master label that is submitted according to § 112.5(d)(1)(iii): *Provided,* That master label sketches submitted in support of an application for license or permit shall be held as long as the application is considered active.

(iii) For finished labels, submit two copies of each finished final container label, carton label, and enclosure: *Provided,* That when an enclosure is to be used with more than one product, one extra copy shall be submitted for each additional product. One copy of each finished label will be retained by APHIS. One copy will be stamped and returned to the licensee. Labels to which exceptions are taken shall be marked as sketches and handled under § 112.5(d)(1)(i).

(iv) For finished master labels, submit for each product two copies each of the enclosure and the labels for the smallest size final container and carton. Labels for larger sizes of containers or cartons of the same product that are identical, except for physical dimensions, need not be submitted. Such labels become eligible for use, concurrent with the approval of the appropriate finished master label: *Provided,* That the marketing of larger sizes of final containers is approved in the filed Outline of Production, and the appropriate larger sizes of containers or cartons are identified on the label mounting sheet. When a master label enclosure is to be used with more than one product, one extra copy for each additional product shall be submitted. One copy of each finished master label will be retained by APHIS. One copy will be stamped and returned to the licensee. Master labels to which exceptions are taken will be marked as sketches and handled under § 112.5(d)(1)(ii).

(2) Mounting:

(i) Each label or sketch shall be securely fastened to a separate sheet of heavy bond paper (8½″ × 11″) in such a manner that all information is available for review.

(ii) Two-or three-part cartons, including ''sleeves,'' shall be considered as one label. All parts shall be submitted together.

(iii)(A) When two final containers are packaged together in a combination package, the labels for each shall be mounted on the same sheet of paper and shall be treated as one label. For diagnostic test kits, the labels for use on the individual reagent containers to be included in the kit shall be mounted together on a single sheet of paper, if possible; if necessary, a second sheet of paper may be used. The carton label and enclosure shall be mounted on separate individual sheets.

(B) If either final container label is also used alone or in another combination package, sets of separate labels for each biological product with which it is used shall be submitted for review.

(iv) When the same final container label is applied by different methods such as paper or screen printing, one of each shall be mounted on the same sheet of paper as one submission.

(3) To appear on the top of each page:

(i)(A) Name and product code number of the biological product as it appears on the product license or permit.

(B) Extra copies of enclosures to be used with another product shall bear the name and code number of the product affected.

(ii)(A) Designation of the specimen as a label or master label: sketch, final container label, carton label, or enclosure.

(B) If two final container labels or multiple parts are on one sheet, each shall be named, and the label or part being revised shall be designated.

(iii) Size of package (dose, ml., cc., or units) for which the labels or enclosures are to be used.

(4) To appear on the bottom of each page: The reason for and information relevant to the submission shall be stated in the lower left hand corner as:

(i) Master label dose sizes approved for code _____.

(ii) Replacement for label, master label, and/or sketch No. _____.

(iii) Reference to label or master label No. _____.

(iv) Addition to label No. _____.

(v) License Application Pending _____.

(vi) Foreign Language copy of Label No. _____.

(e) Special requirements for foreign language labels:

(1) If true, a statement that the label is a direct translation from a corresponding approved domestic label.

(2) If the foreign language label is not a direct translation of an approved domestic label, an English version shall be submitted with an explanation for the difference in texts.

(3) Foreign language portion of a bilingual label shall be a true translation of the English portion. Reference to additional information on the enclosure shall not be made unless that enclosure is also bilingual.

(f) When a request is received from Animal and Plant Health Inspection Service, the licensee or permittee shall submit a list of all approved labels currently being used. Each label listed shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product; and

(2) Where applicable, the size of the package (doses, ml., cc., or units) on which the label shall be used; and

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(g) At the time of an inspection, or when requested by APHIS, licensees or permittees shall make all labels and master labels, including labels approved for use but exempted from filing under the master label system, available for review by authorized inspectors. Such labels shall be identical to the approved label or master label except for physical dimensions, reference to recoverable volume or doses and/or certain minor differences permitted in accordance with § 112.5(c).

(Approved by the Office of Management and Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984; 56 FR 66783, Dec. 26, 1991; 59 FR 43445, Aug. 24, 1994; 61 FR 29464, June 11, 1996; 61 FR 33175, June 26, 1996; 64 FR 43044, Aug. 9, 1999; 75 FR 20772, Apr. 21, 2010]

§ 112.6 Packaging biological products.

(a) Each multiple-dose final container of a biological product which requires a diluent for administration shall be packaged in an individual carton with a container of the proper volume of diluent for that dose as specified in the filed Outline of Production. Each multiple-dose final container of a product which does not require a diluent for administration need not be packaged in an individual carton unless the final container labeling does not contain all information required by the regulations. Such information must be included in or on a carton. Exceptions are provided in paragraphs (c) and (d) of this section and § 112.8.

(b) Single-dose final containers of a product need not be packaged one per carton. For single-dose products which require a diluent for administration, the number of containers of the proper amount of diluent specified in the filed Outline of Production for the number of doses contained in the carton shall be included in each carton.

(c) Poultry products for mass administration (including but not limited to administration through drinking water and spray) and products used in automatic vaccinating systems (including but not limited to pneumatic beak injectors and automated needle injectors) may be packaged in multiple-dose final containers as specified in the filed Outline of Production. Poultry products for manual administration to individual birds shall not exceed 1,000 doses in each final container. Diluent need not be packaged with the final container(s) of the product, but the licensee shall provide the required number of containers of diluent as specified in the filed Outline of Production. The following requirements apply to cartons containing more than one final container of poultry product: